

FAO/WHO
guide for application of
risk analysis principles and
procedures during
food safety emergencies



World Health
Organization



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risk analysis principles and
procedures during
food safety emergencies

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and World Health Organization
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Acronyms

FAO	Food and Agriculture Organization of the United Nations
FSEER	Food safety emergency response
GMP	Good manufacturing practice
IHR	International Health Regulations (WHO) ¹
INFOSAN	The International Food Safety Authorities Network
MACG	Multiagency coordination group
RA	Risk analysis
RASFF	Rapid Alert System for Food and Feed
SOP	Standard operating procedure
WHO	World Health Organization
WTO	World Trade Organization

¹ http://www.who.int/topics/international_health_regulations/en/

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1. Introduction

1.1 Background

An essential part of the Food Safety Emergency Response (FSER) is the process of assessing the risk, making risk management decisions, and communicating risk in the face of time constraints, lack of data and knowledge gaps. While the elements for conducting a risk analysis have been documented by Codex (2007), the process of applying the risk analysis concept operationally during an emergency has not been addressed thoroughly. Some countries do, however, have well-defined procedures for assessing, managing and communicating food safety risks in the context of emergency situations, from which best practices may be derived.

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have developed this document to support countries in applying risk analysis principles and procedures during emergencies in their own national food control systems, as risk analysis is a key component of national FSER planning.

1.2 Purpose of the document

This document was developed to assist countries in understanding essential elements in the application of risk analysis during emergencies, within the framework of their FSER plan. The principles and procedures may also apply to other food safety events that are not necessarily emergencies but that require action to be taken under time constraints and uncertainty.

1.3 Target audience

The target audience includes all national food safety authorities. While it was developed mainly for government agencies, this document may also be useful to organizations that engage in activities in the area of food safety. Recognizing the

importance of relying on effective national food control systems when applying food safety risk analysis during emergencies, the document also addresses the specific needs of countries that are in the process of developing their national food control systems.

1.4 Scope of the document

The document outlines best practice for the application of risk analysis during food safety emergencies, and suggests practical ways of incorporating such processes into existing systems. The food safety risks described in this document include biological, chemical and physical risks associated with food consumption.

This document should not be regarded as a standard, additional to the already established Codex guidelines and related texts on food safety risk analysis, but rather as guidance that is based on a collection of examples of best practice provided by experts from various parts of the world.

1.5 How to use the document

This document provides guidance on how to apply the principles of food safety risk analysis during food safety emergencies. It does not suggest the establishment of new and different risk analysis principles and procedures only for emergencies. Rather, the aim of this document is to provide technical advice on considerations specific to the emergency situation, and to describe useful tools for the application of risk analysis in this context. All components of risk analysis, namely risk assessment, risk management and risk communication, are conducted in an iterative manner both under normal circumstances and during emergencies; therefore, the order of the chapters in this document does not necessarily reflect the timeline of an event.

In order to deliver the functions outlined in the document effectively, food safety authorities must be adequately prepared with arrangements in place before an emergency occurs. These arrangements, including well developed procedures and staff training, form a crucial part of incident preparedness. In this document, major tips on preparedness that are relevant to the particular chapters are summarized in green-shaded boxes with a light bulb logo. In order to facilitate greater understanding of key issues, some real-life examples are included in grey-shaded boxes with a star logo. In addition, relevant advice is highlighted in light green-shaded boxes with an exclamation mark logo.

There are six chapters in this document. The first (current) chapter is the introduction, which describes the background, purposes, target audience and scope, and also outlines two key concepts that are significant to the basis of the document.

The second chapter introduces preliminary activities in risk management, including the initial steps after the recognition of an emergency or an urgent event. The third chapter, “Risk assessment during emergencies”, outlines specific issues to consider in the process of assessing risks during an emergency. The fourth chapter, “Risk management during emergencies”, discusses the key issues and considerations that are particular to emergencies and that are necessary to consider in the management of food safety risks. The fifth chapter, “Risk communication during emergencies”, summarizes the main factors that are critical in the risk analysis process when applied during emergencies. The last chapter concludes the document and provides overall guidance for the application of risk analysis during food safety emergencies.

It is important for readers to study all the chapters in order to capture all the key elements to consider during an emergency. For example, although the chapter on risk assessment provides key advice for risk assessors, the chapter also provides useful and essential information for risk managers and risk communicators, and reading the chapters on risk management and risk communication is also important and useful for risk assessors.

1.6 Key concepts

Although this document can be used as a stand-alone resource, it is strongly recommended that it is read in conjunction with the FAO/WHO guidance entitled “FAO/WHO framework for developing national food safety emergency response plans” (FAO/WHO, 2010; see [Resources](#)).

In addition, it is important to understand the principles for food safety risk analysis in order to apply this guidance document to risk analysis procedures during food safety emergencies. Therefore, it is also strongly recommended that the FAO/WHO document entitled “Food safety risk analysis: a guide for national food safety authorities” (FAO/WHO, 2006; see [Resources](#)) is studied to increase understanding of the general principles and processes needed to arrive at risk-based decisions in food control systems.

1.6.1 National food safety emergency response planning

Food safety emergencies are very diverse and may be described differently according to the food control systems of a particular country. The response to a food safety emergency is scalable, and it may range from “business as usual” to “incident”, “emergency” and “crisis”. However, good planning will foster an effective and timely response.

In a given country, a single body (agency, committee, authority, etc.) theoretically could be mandated to lead the FSER. However, given that food safety emergencies often call for a multidisciplinary approach, FAO and WHO recommend that member states provide the mandate to establish a multiagency coordination group (MACG) to ensure a coordinated approach during emergencies, which should involve relevant government agencies (FAO/WHO, 2010; see [Resources](#)). This document refers to the MACG when discussing decisions and activities that may best be handled in a coordinated manner by multiple agencies.

The risk analysis framework offers a tool that national food safety authorities can use to make significant gains in food safety. Risk analysis encompasses three major components: risk assessment, risk management and risk communication. Risk analysis provides a systematic approach to estimating the risks, in order to identify and implement appropriate measures to control the risks, and to communicate information about the risks and the control measures applied.

It is important to be familiar with all the principles of food safety analysis in order to understand the specific procedures to be considered when applying them in the situation of a food safety emergency or an urgent food safety event (FAO/WHO, 2006; see [Resources](#)).

2. Preliminary risk management activities

Prior to any food safety emergency, it is useful for the national food safety authority to have in place criteria to define what is considered an emergency and a strategy for gathering the necessary information to determine whether a food safety incident meets those criteria. Emergencies may evolve from standard non-emergency food safety situations or may emerge as sudden events.

2.1 Preparedness for food safety emergencies

During a food safety emergency, risk management options may be limited and decisions must be made rapidly. Defining the available risk management options and choosing the most appropriate response may not be straightforward in situations where timelines are constricted and information may not be complete.

Preparedness tip 1

When responding to food safety emergencies, preparedness is key. Creation of various tools, such as templates for data gathering, situation report templates and decision trees, as well as clear and concise reference materials for use during emergencies, can limit the number of decisions that the emergency risk managers will have to make under time constraints. This allows the team to focus on the emergency at hand, and to be able to make decisions on key questions that arise during the event. The use of decision trees¹ and/or templates may also be useful when using established criteria to determine whether a food safety event qualifies as an emergency and to ensure that critical processes are not overlooked.

The objective of any FSER is to prevent further illnesses and maintain public confidence in the food supply. However, during the event itself, the optimal course of

¹ See Figures 2, 3, 4 and 5 on pages 18, 23, 24 and 25.

action may not be evident, and risk managers can benefit from effective tools to simplify the process of choosing risk management options.

2.2 Initial steps after identifying a food safety event

When a national food safety authority receives initial reports of a food safety event that appears to be widespread, difficult to control and/or of serious health consequence, it is necessary to determine: i) the likely magnitude of the event; ii) the need to inform/involve higher officials; and iii) whether the emergency response plan needs to be activated. The following factors may be considered in this context.

- The source of the initial report;

Example: Initial source of information

- Media reports
 - Official food inspectors
 - Laboratory test results
 - Alerts from regional/international partners (INFOSAN, RASFF, etc.)
 - Consumer complaints etc.
- Verification/validation of initial reports by a credible source or through testing;
 - Initiating food safety and epidemiological investigations to determine:
 - Whether food is potentially contaminated with a food hazard
 - Whether severe illness or death is involved
 - Whether the event appears to be localized or widespread
 - Whether the source of the hazard has been identified
 - The involvement of a particular food source
 - The likely scope of distribution of the product (e.g. local, regional, national, international)
 - Whether taking no action could result in widespread illness

Important: Documentation of the outcomes of the risk analysis activities

It is important to document the outcome of these initial steps and the entire process of risk analysis during an emergency. A documentation system should also involve archiving of e-mails, building a database and use of a geographical information system for spatial analysis of the outbreak. These records can be useful when evaluating the emergency response after closure of the event, and are essential when identifying any gaps and needs for improvement.

2.3 Activation of emergency response

Once a food safety emergency has been identified, the national food safety authority will no longer be conducting “business as usual”. Typically, the standard procedures involved in a non-emergency food safety event include all the components of risk analysis. In emergency situations, the risk analysis process generally follows the same order but may be more dynamic and intense, and risk management actions may be taken before the completion of risk assessment.

Once the event has been established to be an emergency, the FSER plan should be activated and a multiagency coordination group (MACG) established. The plan should have defined the roles and responsibilities of those involved in managing emergencies in sufficient detail so that individuals clearly understand their roles, and ambiguity and duplication are prevented. The group should include an expert in communications from the beginning of the process, so that they can develop risk communication materials as required.

In addition, the risk manager should:

- Identify the objectives for that particular emergency response and the data that need to be gathered;
- Evaluate what other relevant factors need to be taken into account;
- Consider the need for inclusion of other relevant agencies/ministries in the MACG;
- Determine which stakeholders may need to be notified (e.g. senior officials, other agencies, affected private-sector establishments); and
- Consider the inclusion of a decision tree to model the initial steps and resulting outcomes.

During the investigation phase of a food safety emergency, an overview of the context and the background information should be developed rapidly for use in further communications.

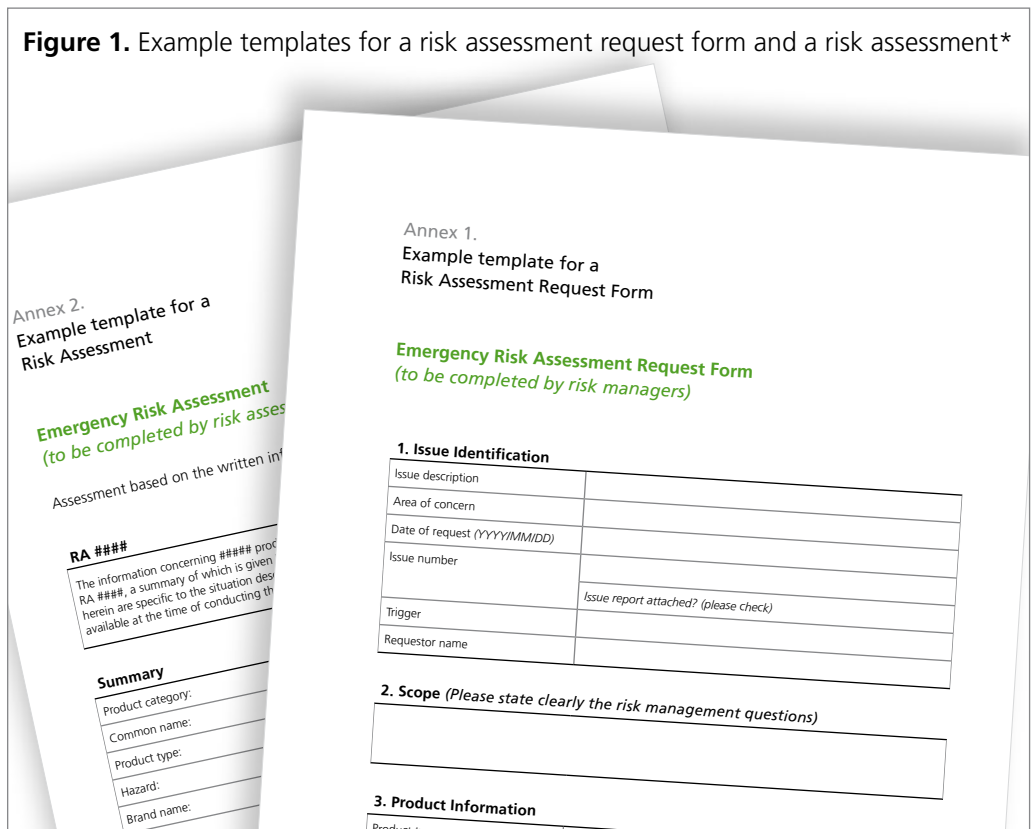
2.4 Formulating targeted questions for risk assessors

During a food safety emergency, interactions between risk assessors and risk managers are likely to be much more rapid, frequent and may be initiated earlier than those that occur during non-emergency situations. At the outset of investigations, the following should be conducted as thoroughly as possible in order to formulate targeted questions for risk assessors.

- Formally engage relevant partners prior to asking the questions, in order to gather additional information that may support the assessment

- Begin to collect and focus information for risk assessment components such as hazard characterization
- For novel/unusual hazards such as particularly virulent pathogens, emphasis should be placed on collecting field data, as far as is possible in an abbreviated time period
- It is useful to have standardised terminologies commonly used by industry and understood by risk assessors and risk managers to reduce any potential miscommunication, delays or errors

Targeted questions should be presented to risk assessors in a standard format (Figure 1; a full example is provided in Annex 1) and clearly defined questions based on currently available evidence should be included.



* See full details of these examples in Annexes 1 and 2 (pages 45 and 49).

3. Risk assessment during emergencies

When risk assessors receive an alert from risk managers regarding an imminent request, it is important for the risk assessors to screen the incoming as well as other available data and information rapidly, to be able to decide the appropriate methodological approach and the scope of the risk assessment.

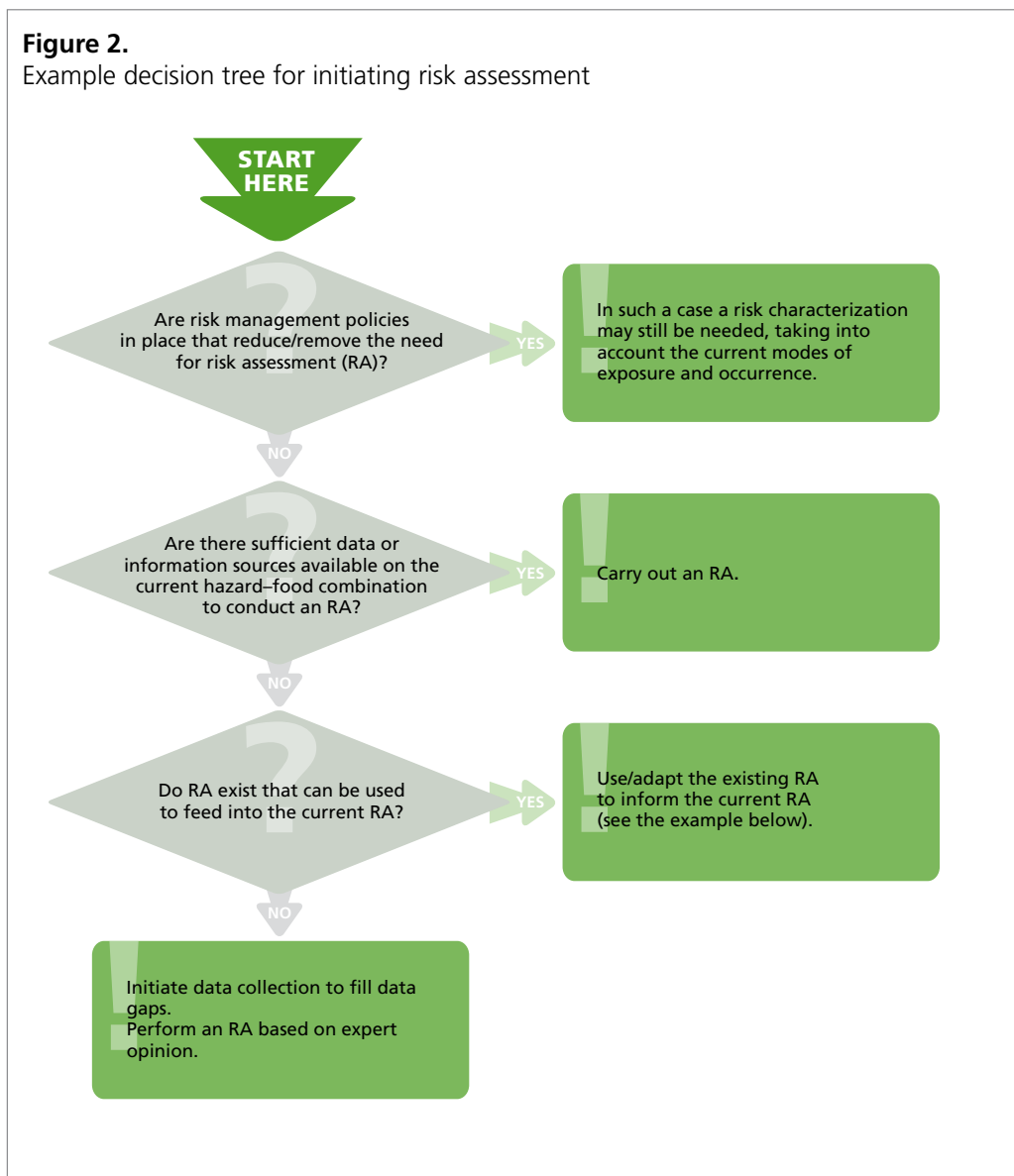
Decisions will need to be made on whether: i) food safety standards are in place that could reduce or eliminate the need for a risk assessment and ii) the data and information are sufficient to conduct one. It is also important to assess whether: iii) existing risk assessments can be used to feed into the current risk assessment and iv) a risk assessment needs to be conducted. A decision tree is presented in Figure 2.

Given the time constraints present during emergencies, it is unlikely that a full risk assessment can be conducted. However, it is important that the risk assessment performed during an emergency is robust enough to stand up to any questions posed by risk managers and/or senior officials (i.e. it must be defensible). In addition, it is usually impossible to initiate new empirical studies to fill data gaps within the short deadlines that are necessary.

Example: Eyjafjallajökull volcanic eruption

In the absence of data on the ash composition in Eyjafjallajökull volcanic eruption in 2010, generic data on ash composition from previous volcanic eruptions were used to assess the possible risks to public and animal health from the contamination of feed and the food chain due to possible ash-fall following the eruption of the Eyjafjallajökull volcano in Iceland. (<http://www.efsa.europa.eu/en/efsajournal/pub/1593.htm>)

Figure 2.
Example decision tree for initiating risk assessment



When conducting a risk assessment during an emergency, it is important to note that there needs to be more frequent and a higher level of communication between risk assessors and risk managers right from the start of the emergency.

In spite of the urgent nature of the incident, peer review of the risk assessment still needs to be considered, whether internally or externally, especially in situations where data are limited or the issue is particularly contentious, to rule out possible oversights and misinterpretations.



Preparedness tip 2

For risk assessment during emergencies, tools already developed could be useful in assessing risk rapidly in the absence of complete information. Examples of such tools include:

- A database on structural groups of similar chemical substances for which toxicological data exist (surrogate data) that can be used to infer hazard characteristics for substances for which no data are available;
- A national food consumption database or access to international databases on food consumption, or those of other countries;
- Established partnerships with external experts and external advisory groups for consultation
- Specific templates to collate the relevant data on a given incident, along with a situation summary template and the risk management questions to address (this can help to expedite initiation of the risk assessment); and
- A compilation of reference values (exposure limits) published by regulatory agencies.

3.1 Specific issues to consider in the process of assessing risks during an emergency

With a view to the short time frame usually available for conducting a risk assessment during an emergency, if sufficient expertise is not available in the country, or if the emergency is affecting multiple countries, it is advisable to contact relevant competent authorities and/or scientific experts from other countries. The scientific information to be used could benefit from sources with local knowledge, or persons with tacit knowledge of the event or process involved. This allows rapid collection of data and information relevant to the scientific questions that need to be addressed.



Preparedness tip 3

Prior to a food safety emergency, it is helpful to establish formal and informal relationships to obtain relevant data and information from other countries. For formal collaborative arrangements, memoranda of understanding may need to be in place to help alleviate concerns over privacy and data security/ownership issues. FAO and WHO can be good sources of contact information for countries and relevant institutions with which to establish such collaborations.

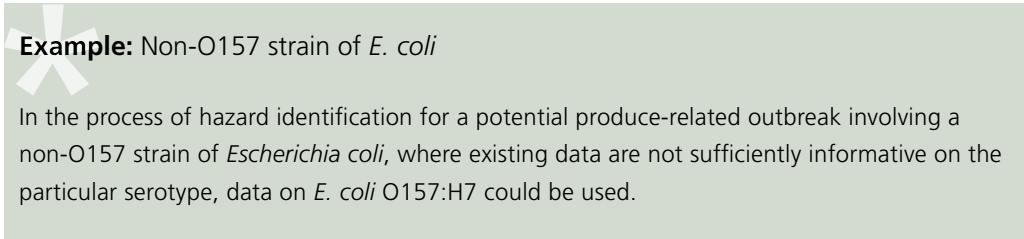
The scientific information to be used in the development of the risk assessment falls into two categories: i) pre-existing information (e.g. literature reviews and risk assessment available online, or consumption survey data and statistics) and ii) data

specific to the incident that are based on food safety investigations and/or epidemiological investigations. Countries may have to consider how much weight to assign when assessing the evidence obtained by these different methods and by other areas of investigation (Health Canada, 2011; see [Resources](#)). In addition, some weight may be given to risk analyses/assessments done by industry or company experts that may be relevant; for example, industry may have already mapped out the product/process flow that should speed up the exposure assessments. Careful consideration needs to be given to the assessment of national capacity and resources for analytical work (laboratory testing), epidemiological investigations and risk assessment activities. Expert opinion(s) may also be considered as another source of information for the risk assessment.

The risk assessment performed during an emergency should be reviewed more rapidly, through an active and frequent communication among risk assessors, as well as between the risk assessors and risk managers. The risk assessment is likely to require updating as the situation unfolds and more data become available. See also the box on page 27 in Section 3.3 for further information on this point.

3.1.1 Hazard identification

In some situations in which the hazard is not fully identified, or existing data are insufficient and when there is not enough time to generate data, existing data could be used as a surrogate to address scientific questions. Expert opinion could also be used to review the assumptions made.



Example: Non-O157 strain of *E. coli*

In the process of hazard identification for a potential produce-related outbreak involving a non-O157 strain of *Escherichia coli*, where existing data are not sufficiently informative on the particular serotype, data on *E. coli* O157:H7 could be used.

Development of hazard/pathogen definition documents that can be modified/updated easily in an emergency would be ideal. In particular, identifying specific attributes that are the main contributors to severity would be helpful, especially in situations where a new hazard has been discovered. In this regard, any specific attribute of the new hazard could be compared to what is on file and this may facilitate the process of hazard identification.

Whenever feasible, validated rapid test methodologies should be used to identify the hazard as far as possible. If there is no validated test method available in-house, it will be necessary either to scan the published literature quickly, contact the international scientific community for scientific advice, or as a last resort develop a method that is fit for purpose as rapidly as possible.

3.1.2 Hazard characterization

Existing data from toxicity studies, guidance and guideline values, as well as dose–response data or models, may be used in order to expedite the risk assessment. Sources of such data such as those available in the reports and monographs of evaluations performed for other organizations or other expert meetings may be useful (see [Resources](#)).

In the absence of available dose–response data, an approach that errs on the side of caution should be applied and the entire population could be considered to be sensitive to the hazard.

Example: Methylmercury

The studies available show that the embryo and fetus are the most vulnerable life stages with respect to the adverse effects of methylmercury, and a provisional tolerable weekly intake (PTWI) of 1.6 µg/kg body weight was established on that basis. By definition this PTWI covers the whole lifetime, but in the case of adults (except pregnant women) intakes of up to about two times higher than the existing PTWI would not pose any risk of neurotoxicity.

3.1.3 Exposure assessment

It is imperative to consult existing national food consumption data in order to inform the exposure assessment. In the absence of representative national consumption data, data from household food purchase surveys or similar types of national statistical data or predictive models could be used. In addition, data from other countries with similar food consumption habits, or international data e.g. WHO GEMS/Food, can be considered. Assumptions regarding the validity of these data and their appropriateness need to be documented properly and stated in the risk assessment. Different strategies of exposure assessment will be needed, including the use of modelling and measuring approaches, in order to determine the best possible exposure assessment.



Example: Dietary exposure assessment

In any dietary exposure assessment, it is important to determine the concentration of the microorganism or chemical residue in the food at the time of consumption. Factors to consider are sampling data, time between sampling and likely consumption, storage temperature, microbial growth (existing predictive models can be very useful; see COMBASE, <http://www.combase.cc/>), chemical degradation rates, and inactivation or degradation through cooking or other preparation methods. Based on this information, the concentration at the time of consumption can be estimated. Ideally, each factor is described by a distribution as a basis for a probabilistic analysis.

The contamination at the time of consumption is then used with national food consumption data to estimate dietary exposure to the microorganism or chemical residue. At the very least, exposure from average (or most likely) consumption patterns, as well as worst-case exposure due to high consumption of contaminated food, should be investigated. If a probabilistic analysis is performed, the 95th or 99th percentile might be taken as a high-exposure scenario. Finally, the consumption analysis should also consider vulnerable populations, such as pregnant or breastfeeding women, infants, children and immunocompromised individuals.

It should also be noted that it is likely that the exposure assessment will need to be refined as new information is collected.

3.1.4 Risk characterization

When conducting a risk assessment during an emergency, the initial review of the information available will often need to be of a qualitative, or potentially semi-quantitative, nature because of constraints on time and information. Decision trees can be very helpful in expediting the identification and quantification of the level of risk associated with a particular commodity. They can also aid in explaining the different levels of risk to risk managers and risk communicators. Examples of decision trees for chemical and microbiological risk assessment are shown in Figures 3 and 4 respectively. In addition, an example of a generic decision tree for a hypothetical *Salmonella* risk assessment is presented in Figure 5.

Figure 3. Example decision tree for chemical risk assessment

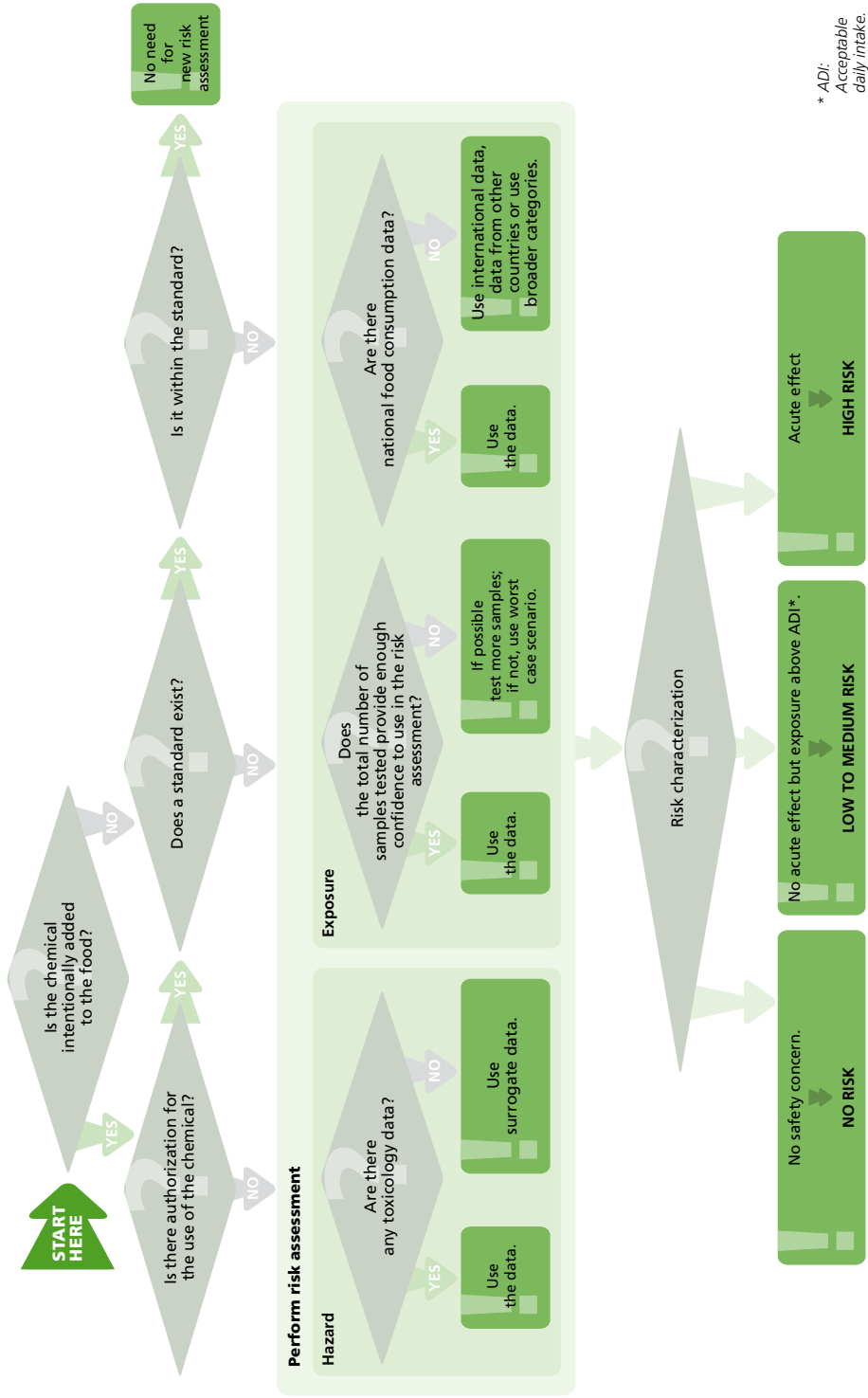


Figure 4.
Example decision tree for microbiological risk assessment

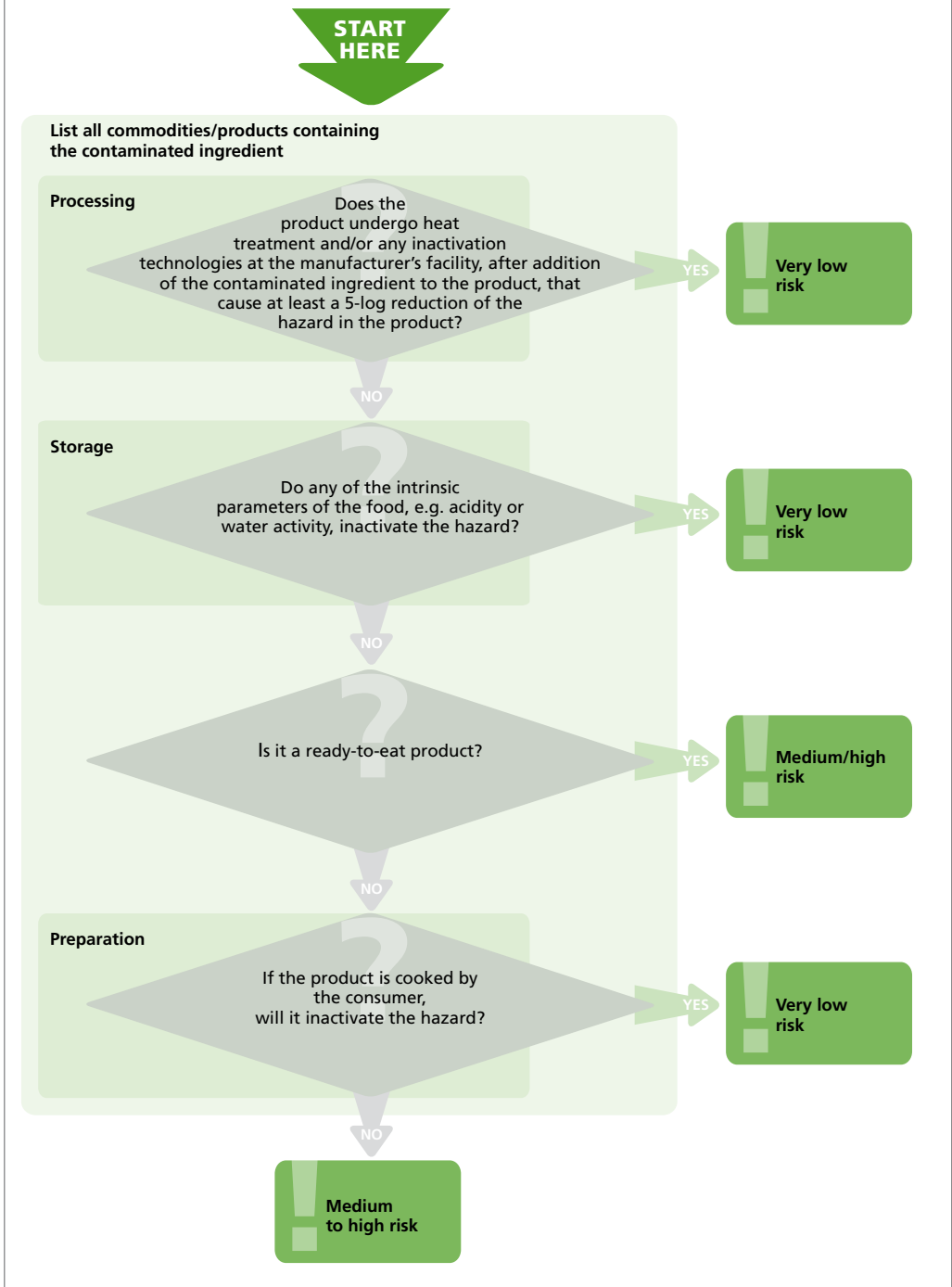
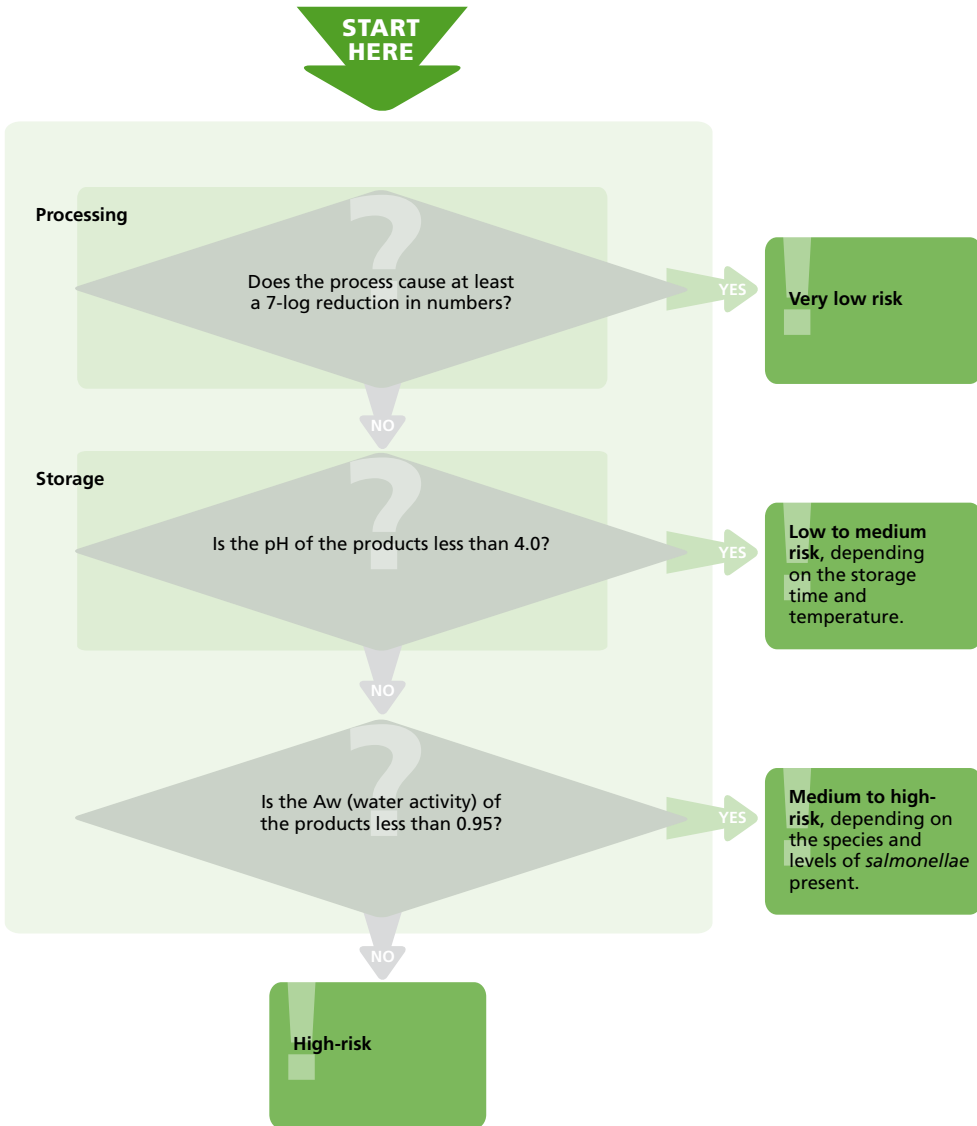


Figure 5.

Example Decision tree for a hypothetical *Salmonella* risk assessment in ready to eat products



3.2 Importance of addressing limitations and uncertainties in risk assessment

Given that the risk assessment will be conducted over a short period of time in an emergency situation, there may be considerable data gaps and uncertainties, which may affect the robustness of the risk assessment.

Preparedness tip 4

To ensure that there is a good understanding of the uncertainties in the existing data, and therefore the robustness of the risk assessment during an emergency, it is important to develop a prior awareness of the existence and causes of such uncertainties. This will involve regular dialogue between risk assessors and risk managers during non-emergency situations.

When risk assessors discuss the situation with risk managers and risk communicators during an emergency, it is important to state that the risk assessment is based only on the current knowledge and data available. Uncertainties that arise during the development of the risk assessment need to be documented and communicated to the risk managers as early in the process as possible. If these uncertainties are not communicated properly, misinterpretation can occur and further communication to stakeholders, including consumers, can be affected.

Documentation of uncertainties becomes more important during emergencies because decisions, some of which may change as new information comes in, may have to be made in the absence of a complete data package. Additionally, the documented limitations of the risk assessment may need to be expressed in a way that can be understood by a non-technical audience.

It is important to communicate the overall picture of the uncertainties, as well as: i) addressing what can be done to reduce the uncertainties and ii) identifying what cannot be done in a short period of time. For example, the generation of completely new data on hazard characterization is not possible during an emergency, but further investigation of the particular event (e.g. to collect more epidemiological or microbiological data) may be possible to reduce the uncertainties.

3.3 Revision of the risk assessment as data/knowledge become available

After the initial risk assessment, further data may become available to address the most critical gaps. Depending on the emergency situation, several revisions of the risk

assessment may be needed. The risk assessment should be revisited on a regular basis in a forum such as the MACG to ensure that all parties are able to contribute any new evidence that may help to further refine or change the assessment, and thus inform the risk management options and decisions. Such a process for effective interaction between risk assessors and risk managers is important and needs to be agreed upon and be included explicitly in the FSER plan.

Important: Interaction between risk assessors and risk managers

Efficient interaction between risk assessors and risk managers during an emergency situation can be achieved through frequent/regular meetings, both formal and informal, and by using all available channels such as phone calls, e-mail and teleconferencing. To ensure confidentiality, it is preferable to establish a closed system of communication. However, the key to effective interaction is the state of preparation prior to the emergency, including the establishment of networks, identification of key personnel that will be involved in handling the emergency, and having an adequate infrastructure in place for effective communications. This may include having a good information management/technology support system in place.

4. Risk management during emergencies

When determining what actions to take, the focus on protecting public health and safety will usually outweigh all other factors and will be crucial in maintaining/restoring confidence in the market and among consumers. However, risk managers must consider the interests of all stakeholders, and the economic and societal impacts of the situation.

Preparedness tip 5

In order to allow the MACG to focus on managing the food safety emergency effectively and efficiently, it is imperative that as much preparation as possible is undertaken in advance. This preparation could include pre-developed risk management options, documents, guidance tools (e.g. templates, checklists and decision trees) and structures and rules for removal of products from the market. Advance preparation will also reduce the need to negotiate acceptable approaches during an actual emergency, reduce the number of decisions that need to be made and will reduce the stress on those involved in managing the emergency.

Example: Materials that can be prepared beforehand

- Risk categories, including definitions, descriptions and examples
- Risk management options appropriate to individual risk categories
- Implementation approaches
- Communication approaches appropriate to individual risk management options, including communication with international bodies and other governments
- Pre-defined roles and responsibilities of the MACG members

It is important to agree in advance whether risk assessments should contain advice on risk management options for different types of food emergency, but there may be occasions when the agreed approach does not suit the needs of a particular emergency, and decisions need to be taken ad hoc.

Documentation of all the risk management activities performed during an emergency is essential and critical. See relevant point in the box entitled “Documentation of the outcomes of the risk analysis activities” on page 14.

4.1 Developing risk categories, possible management options and communication methods

Developing a well-defined system for the categorization of food safety emergencies will enable rapid and consistent risk management decisions for a given type of hazard (e.g. chemical, microbiological, physical), and the scale and/or severity (e.g. high, medium, low) of the food safety emergency. While a categorization system will not be able to cover all contingencies completely, the system should be flexible enough to provide a valuable framework for dealing with an unusual occurrence. An example of a matrix to aid in making rapid and consistent risk management decisions and choosing risk communication approaches is shown in Figure 6 (see page 30).

Categorization of levels of emergency allows the advance identification of the types of risk management option and communication strategy appropriate to each level. For example, a low level event would usually be controlled more easily and managed with less risk management intervention and fewer resources than a high level event, which might be very widespread, difficult to control or have severe consequences. Consideration should be given to how the decision will be made to assign the category during an emergency; for example, whether this is the responsibility of the risk assessor, the risk manager or both in consultation.

Preparedness tip 6

Prior to an emergency, the national food safety authority should communicate the risk categorization system and risk management options to industry. This will enable industry to align emergency management protocols with government arrangements and to foster effective emergency management working relationships.

Figure 6.

An example of a matrix to aid risk management decisions and communication strategy

If there is a high level of concern from the general public and/or media, there may be a need to scale up the response (management options) and/or communication strategy.

		Management options	Public risk communication options
Risk category	Low	<ul style="list-style-type: none"> • Consider detention/seizure of product • Consider product recall (retail) 	<ul style="list-style-type: none"> • Public alert or posting • Passive communication approach
	Medium	<ul style="list-style-type: none"> • Detention/seizure of product • Recall of product 	<ul style="list-style-type: none"> • Active announcements (press release)
	High	<ul style="list-style-type: none"> • Detention/seizure/destruction of product • Recall of product • Enhanced monitoring of recall effectiveness • Additional investigation (other potential products) • Cooperative activities with partner agencies, medical community, technical experts, etc. • Community outreach activities (help-lines, social services, etc.) 	<ul style="list-style-type: none"> • Enhanced communication practices, with frequent updates • Active announcements (press release, press conference) • Updates through multiple media (radio, TV, websites/portals, social media, focus groups) • Establish two-way communication, using hotlines, public meetings

4.2 Identifying management options

The risk management options for each level of risk category need to take into consideration the country's available resources and capacity. During an emergency, if the national food safety authority recognizes the need for additional resources and capacity, international counterparts or organizations could be consulted to share information or to seek feedback and advice.

Example: Management options

- Collect and analyse affected or potentially implicated product(s)
- Control imports
- Stop further production and distribution
- Remove product(s) from the market (voluntary, mandatory)
- Post public alerts and warnings
- Use active communication strategies
- Detain or seize product(s)
- Recondition product(s)
- Destroy product(s)
- Criminal prosecution

The national food safety authority needs to list all possible risk management options at this stage. It is important to ensure that the risk management options are consistent with international laws or agreements and that they are communicated to international and regional authorities as required (e.g. WHO under the IHR, WTO). Where a national food safety authority determines that the risk management measures adopted may have an impact on the importation of a particular commodity from a particular country or region, there is also an obligation to notify the measures to the WTO.

It is important to note that in a complex emergency situation the initial risk assessment is likely to be based on incomplete information, and the assessment may need to be refined as further evidence or information becomes available. Risk managers should review the initial risk assessment to ensure that key questions have been addressed and that the risk assessment reflects the actual food safety emergency as far as possible.

The national food safety authority may engage industry and other interested partners to gather further information where appropriate, because this may assist in establishing the extent of the emergency and may further inform the risk assessors. For example, this approach may be useful in cases where a particular problem has been identified in an ingredient that may be incorporated in several types of product. Also, industry or other concerned stakeholders may request information to determine whether their own products may be implicated.

4.3 Key factors for selection of risk management options

Several key factors should be considered when selecting risk management options during a food safety emergency. Using a risk categorization system may serve as a useful guide in selecting risk management options. However, other factors may also influence the national food safety authority's choice of options, including those listed below.

- **Capacity issues:** If there is a limited capacity to implement risk management or to perform laboratory analyses, the national food safety authority may choose to seek analytical services from counterparts in other countries, or assistance from international organizations such as regional or international laboratories.
- **Uncertainty about the nature of the risks:** Uncertainties may have an impact on the timing and selection of risk management decisions. For example, the decision may be either to wait until additional information becomes available or to take action to protect consumers in the absence of a full assessment.
- **Public expectations and perceptions:** Public demands for information are likely to be heightened during food safety emergency events, so national food safety authorities may be put under pressure to take more stringent actions. Risk communication is particularly important where the selected risk management option may appear to be less stringent than expected by the public.
- **Legal considerations:** The national food safety authority should consider the extent to which the legal framework and legislation support risk management implementation.
- **Industry considerations:** Industry support and cooperation can be a key factor in determining what types of action are feasible/desirable.
- **International considerations:** Risk management approaches taken by other countries, and trade implications, should also be considered.
- **Other considerations:** For example, the responses to previous events, if applicable, should be considered to improve consistency.

4.4 Implementation of risk management decisions

In an emergency situation, the implementation of risk management decisions is likely to call for the involvement of multiple agencies and services. In some instances it may also involve other organizations that are not commonly involved in food safety activities. The work of the agencies and services involved may need to be coordinated by a MACG, as outlined in the FSER Framework (FAO/WHO, 2010; see [Resources](#)), to ensure risk management decisions or control measures are implemented rapidly.

Preparedness tip 7

Examples of the issues that could be considered in the preparation of emergency response plans include:

- The need to encourage agencies, industry and relevant organizations to prepare emergency protocols and plans;
- The importance of having suitably trained staff available to relieve or assist those involved in emergencies that occur over an extended period of time or are very widespread;
- The legal authorization – the preparation of templates for seeking or establishing appropriate legal authorization may be beneficial;
- Prepared communication may help to coordinate the implementation of an effective risk management response; and
- The capacity to obtain additional funding to cover complex risk management actions; countries may seek to establish emergency funds for high-level emergencies.

Closer industry consultation and monitoring will be important during the implementation stage, because industry will need to be involved in implementing the risk management decisions, such as removing a product from the market or taking corrective action. In this context industry could involve food producers, importers, manufacturers, distributors and retailers. In dealing with industry during an emergency, it is important to have a legal basis for cooperation, but where the legal basis is ineffective there may be other more effective mechanisms, such as advice to the public or consumer responses.

Where the emergency relates to a widely used ingredient, it may be difficult to trace the distribution or source of the ingredient implicated. Given that many supply chains are very complex and may involve imported products or ingredients, industry expertise and international networks may provide important sources of advice. Any requirement for notification of actions internationally should be determined at this stage.

4.5 Monitoring and evaluation of the outcome/results

During an emergency, monitoring and evaluation of the effectiveness of the risk management option and its implementation are essential to ascertain whether the hazard is being controlled effectively, or to identify any additional control measures necessary. If monitoring indicates that the risk management approach is not controlling the hazard effectively, further information and risk assessment may be needed or additional risk management measures may need to be implemented. To accomplish this task, an efficient monitoring or surveillance system is necessary.

Alternatively, monitoring may indicate that the hazard has been controlled sufficiently to allow a scaling down of the risk management response or the conclusion of the emergency (stand down). Communicating any changes in the risk management approach will be important in maintaining public confidence in the handling of the emergency and in advising industry of any changes to the actions needed to manage the hazard.

Monitoring and evaluation activities will vary according to the type of emergency and the capacity of the countries involved.

Given that emergency situations can have serious consequences, the implementation of a process of evaluation enables the effectiveness of individual emergency responses to be assessed and improvements to the process to be identified and implemented. It is important to assess the performance of the emergency risk management activities after the conclusion of the emergency. The evaluation should

Example: Monitoring and evaluation activities

- Monitoring imports at the border
- Collecting and analysing samples of implicated products or potential substitutes for products that have been removed from the market
- Requesting information or test results from other countries or international organizations
- Obtaining domestic or international epidemiological data

be conducted even if the approaches have not been pre-established. The results of the evaluation will be useful in identifying any regulatory or other changes that may be required to prevent future occurrences.

5. Risk communication during emergencies

Communication during emergencies is often very different from communication under non-emergency circumstances. Communication needs to occur frequently during an emergency because there is usually an urgent demand from various stakeholders for timely up-to-date situation reports. Often such communication messages need to be developed in a very short time frame and in consultation with a wider range of agencies than in normal situations. All risk communication should be coordinated through one individual or office, to ensure consistency of messaging and to avoid confusion.

Preparedness tip 8

In an emergency situation, effective communication is critical and requires advance preparation to provide timely, open and accurate exchange of information to all stakeholders and partners. This ensures a common understanding of the details of the food safety emergency and maintains confidence in the government's handling of the food safety emergency.

In situations where the food safety emergency may not be fully understood, communication messages may need to change rapidly as more information is obtained or as risk management actions are changed. On some occasions, risk communication is expected to be conducted under high levels of media scrutiny and pressure. Under these circumstances, it is important to make sure that appropriate messages reach the target audience.

Therefore, throughout the incident, the emergency response team needs to include members who have good knowledge of effective risk communication methods and who can provide advice to the emergency response team and serve as, or provide advice to, the spokesperson delivering the public messages.

5.1 Communicating the rationale for the selection of control measures

In communicating the rationale for the selection of control measures, it is important to maintain transparency and to provide enough information without causing unnecessary concern or over-reaction. Explaining and describing how uncertainty has been dealt with in selecting the control measures is of utmost importance.

It is important to consider the public's concern by monitoring the perception of the risk and consumer behaviour in the community in relation to the specific food emergency and tailoring the communication messages accordingly. It is also important to identify the different target audiences the communication is aimed at, and to find easy and clear ways of communicating with these groups. Using analogies or examples can help the public put the risk into perspective.

Example: Iodine in soymilk

When high levels of iodine were detected in one brand of soymilk in Australia in 2009, people were advised not to drink this product because even small daily amounts, as little as 50 ml, could cause thyroid problems in some susceptible people.

5.2 Communication with industry during the risk analysis process

An effective working relationship between government and industry facilitates a more efficient and effective response and earlier resolution to an emergency, and could also benefit industry during the process of reintroduction of products to the market following closure of the emergency.

Preparedness tip 9

Establishing contacts and agreeing on the arrangements that will operate between industry and government during emergencies will be beneficial. These arrangements could be agreed with industry associations, individual companies, customs brokers and major importers and exporters. Contact information may be available from official sources such as licensing or registration databases.

Communication between industry and government during a food emergency serves several important purposes for the following reasons.

- Industry needs to be aware of the rules and guidelines they will need to operate under during an emergency;
- Communication messages from government and industry to the public during an emergency should be consistent and complementary. (It is ideal for industry to develop its own communication plans and approaches beforehand for use during an emergency);
- Industry may be an important source of information for the national food safety authority when managing an emergency (e.g. product or ingredient tracing information, complaints, trend data);
- Industry needs to be able to respond appropriately and quickly to risk management actions and any changes; and
- The national food safety authority should provide industry with information on how the investigation is conducted, the focal point, the proposed risk management options and the legal basis for these activities.

Keeping open communication channels with the industry concerned should result in effective cooperation and compliance with risk management decisions. However, there may be occasions when there is breakdown in the lines of communication, and other approaches to enforcement and monitoring may need to be adopted and implemented.

5.3 Risk communication to the general public

The initial public communication at the onset of an emergency is critical and it can often influence public perception of the ability of the national food safety authority to manage the emergency. Public reactions, both real and anticipated, can influence the subsequent direction or management of the investigation. Therefore, it is essential that messages are as accurate as possible, timely, consistent, complementary, demonstrate confidence, are well targeted to the audience and address the concerns of the public.

Depending on the nature of the emergency, it may be important to start public communication activities early in the emergency, rather than waiting until all control measures have been implemented. It may also be necessary to develop messages to counter inaccurate statements or messages in the media or those made by interest groups.

Important: Risk communication to the general public


Communication about a food safety emergency should not underestimate the gravity of the situation but indicate as clearly as possible to the public.

- What is known about the food safety emergency
- The food products involved
- What the risks are and whether they are known
- What levels of exposure could be harmful
- What the public should do if they have consumed or obtained affected products
- How to access additional information

When communicating with the general public during an emergency, it is ideal that an agency is identified to take the lead on communications, and that one or more appropriately skilled spokespersons be appointed. This may reduce the chance of inconsistent government messages being reported, and should build confidence in the response. Where more than one government agency is providing public communications, messages should be shared to facilitate consistency and complementarity and the procedures and timelines should be agreed in advance.

Risk communication needs to occur in two directions. As well as providing information it is important for the food safety authority to provide a mechanism for the public and other groups to seek assistance or information, or to be able to provide information to government, for example through a telephone helpline, call centre or web portal.

In the early stages of an emergency there may be uncertainty about the extent or cause of the hazard or the control measures needed to manage the situation. When communicating limitations in knowledge to the general public, it is important to consider public perceptions and the general level of knowledge about an issue. It could be valuable to have consultative groups (e.g. stakeholder groups) available during emergencies to obtain feedback in order to understand the concerns of the stakeholders. The information obtained from these groups could be useful in identifying risk management options and in developing risk communication strategies and messages. This will enable information to be targeted appropriately and may reduce unnecessary public concern and consequential behaviours.



Example: Consequence of unnecessary public concern

Concern about one type of seafood may result in people avoiding all types of seafood unnecessarily, which could have a negative nutritional impact, lead to the collapse of an industry and have a negative economic impact on the country.

To ensure that communication reaches all target audiences, a range of vehicles should be considered, for example radio, television, the Internet, including smart phone applications, and use of health or field officers and organizations. The communication vehicle and the way information is presented should be tailored to the needs of the audience, including targeting those at greatest risk and considering literacy and the languages spoken. If possible, the effectiveness of the communication should be monitored so that the approach can be changed if necessary. An indirect way of monitoring the impact of the communication is to assess the level and nature of media reporting and the reaction to government messages (e.g. mainstream media, social media, blogs).

5.4 Communication with relevant international/regional bodies

During emergencies that involve products in international trade it is essential for national food safety authorities to establish contact with international counterparts in order to share data and other pertinent information. Communication early in an emergency can provide national food safety authorities with the opportunity to discuss the emergency and to work through approaches to risk assessment prior to their implementation. This may allow countries to combine resources, determine ways to address the emergency collectively and support countries that may not have the capacity to undertake comprehensive risk assessments.

Communicating in advance of risk management decision-making may facilitate agreement on the risk assessment and risk management approaches and lead to greater consistency in the emergency response and an increase in public confidence in the national food safety authorities of the respective countries.

In cases that appear to be isolated to domestic products, it could be helpful to notify international counterparts, because products may be exported, even through informal channels (e.g. Internet purchases). The International Food Safety Authorities Network (INFOSAN) is a global network managed by FAO and WHO which can be

used to help disseminate such information, and can serve as a valuable source of information, advice and support for the national food safety authority. The INFOSAN secretariat can also help to facilitate cooperation when multiple countries are involved in a common food safety emergency.

6. Conclusions

A variety of situations could lead to the need to activate an FSER. Countries will need to describe an emergency in terms of their own food control system, resources and capacity; therefore an emergency could lead to a different emergency response depending on the situation of a given country. However, the application of risk analysis during an emergency should follow the same principles as risk analysis applied under normal circumstances. There will be a preliminary risk management activity, risk assessment, risk management and risk communication. The only differences in an emergency situation are the factors affecting the decision-making, which could include: time pressure, the likelihood of increased uncertainty, an increased need for multiagency collaboration, involvement of officers at a higher level and a strong demand for timely communication.

Thus, for an emergency response, preparedness is key. Prior to any food safety emergency, the national food safety authority could consider putting in place the followings:

- A national FSER plan and team;
- An organizational scheme involving the MACG;
- Data and information storage for food hazards and previous risk assessments;
- Scientific advisory bodies (internal and external) to review the evidence during food safety events;
- Tools to facilitate decision-making (e.g. templates, checklists, decision trees), and management options; and
- Effective tools and strategies for communication with all stakeholders, including the concerned food producers and the consumers.

Consistent documentation and effective communication are essential during emergencies. The effectiveness of a documented emergency response can be assessed after closure of the event, and the materials used as “lessons learned” to improve future emergency responses.

Annexes

Annex 1.

Example template for a Risk Assessment Request Form

Emergency Risk Assessment Request Form (to be completed by risk managers)

1. Issue Identification

Issue description	
Area of concern	
Date of request (YYYY/MM/DD)	
Issue number	
	<i>Issue report attached? (please check)</i>
Trigger	
Requestor name	

2. Scope (Please state clearly the risk management questions)

--

3. Product Information

Product type	
Common name	
Brand name	
Container size	
Lot code	
Best before date	
Domestic/Imported	
Manufacturer name	
Manufacturer address	

(Cont.)

Emergency Risk Assessment Request Form *(continued)*

3. (cont.) Product Information

Importer name	
Importer address	
Country of origin	
Manufacture date	
Import date	
Container type	
List of ingredients	
Label (claims)	
	<i>Labels attached? (please check)</i>
RTE product or not?	
Cooking instructions	
Storage instructions on label	
pH	
Aw	
Salt (%)	
Moisture (%)	
Other preservatives, additives or processing aids	
Storage conditions	
Shelf-life duration	
Production date	
Pack date	

4. Distribution/Consumer Information

Quantity manufactured/imported	
Quantity distributed	
Depth of distribution (HRI, retail, consumer)	
Geographical distribution	

(Cont.)

Emergency Risk Assessment Request Form (continued)

4. (cont.) Distribution/Consumer Information

Number of people who consumed suspect food	
Number people ill/reaction	
Food history (3 days)	
Method of food preparation by consumer (oven, stovetop, microwave, etc.)	
Adverse reactions reported (illness, allergy, injury, etc.) (Y/N) and brief description	
Off-condition reported (off-odour/appearance, bulging can, etc.) (Y/N)	
Date/Time of consumption	
Onset of symptoms	
Symptoms	
Duration	
Medical attention sought (Y/N)	
Diagnosis confirmed?	
Where food was consumed (home/ restaurant/event)	

5. Laboratory Analysis

Product tested? (Y/N)	
Method used	
Laboratory	
Sampled by? (e.g. inspector, company)	
Lot code	
Results of ALL samples tested, including not detected (micro: presumptive/detected/not detected/level/ pending results; Extraneous material: size, shape, sharpness)	
	<i>Labels attached? (please check)</i>
Results of other products tested	
Results of environmental testing	
	<i>Images attached? (please check)</i>

(Cont.)

Emergency Risk Assessment Request Form *(continued)*

6. Distribution/Consumer Information

Sampling method and other sampling information (composite, at the plant, manipulation, sanitation, aseptic conditions, carcasses, trims, core drilling, etc.)	
Sample sealed/intact or opened/consumer?	
Product process flow (preparation steps, packaging, scheduled process, time/temperature, cutting, etc.)	
Sanitation practices and process controls (good manufacturing practices, GMPs; corrective action requests)	<i>SOP attached? (please check)</i>
Company definition of a lot or batch (e.g. sanitation to sanitation, slicing lot, etc.)	

7. Extraneous Materials

Outline all information pertinent to the nature of contamination (glass, plastic, insects/rodents, live or dead, infestation, shells in shelled nuts, pits in pitted peaches) its incidence in a lot and size, texture and potential for harm (include picture when available).

8. Situation Summary

--

9. Additional Relevant Information and Comments

--

Date/time request form received:	
Date/time all information received:	

Annex 2.

Example template for a Risk Assessment

Emergency Risk Assessment (to be completed by risk assessors)

Assessment based on the written information provided in Annex 1.

RA

The information concerning ##### produced by ##### has been reviewed and an assessment contained in RA ####, a summary of which is given below. Please note that this RA and any recommendations presented herein are specific to the situation described below, unless otherwise stated. It is based on the information available at the time of conducting the assessment.

Summary

Product category:	
Common name:	
Product type:	
Hazard:	
Brand name:	
Container size:	
Lot code:	
Storage requirements:	
Best before date:	
Domestic/Imported:	
Manufacturer name:	
Manufacturer address:	
Country of origin:	
Manufacturing date:	
Quantity manufactured:	

(Cont.)

Emergency Risk Assessment *(continued)*

(cont.) Summary

Quantity distributed:	
How/When problem was discovered:	
RA request:	
Date request received:	
Originator:	
File location:	
Nature of health risk:	
Relevant factors:	

Resources

- **Codex.** 2007. *Working principles for risk analysis for food safety for application by governments* (CAC/GL 62-2007). Available at:
http://www.codexalimentarius.net/download/standards/10751/CXG_062e.pdf
- **FAO/WHO.** 2006. *Food safety risk analysis. A guide for national food safety authorities*. Rome, FAO/WHO. Available at:
<ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf>
- **FAO/WHO.** 2010. *FAO/WHO framework for developing national food safety emergency response plans*. Rome, FAO/WHO. Available at:
<http://www.fao.org/docrep/013/i1686e/i1686e00.pdf>
- **Health Canada.** 2011. *Weight of evidence: factors to consider for appropriate and timely action in a foodborne illness outbreak investigation*. ISBN: 978-1-100-18531-6. Ottawa, Health Canada.
- **Institute of Food Research.** *Combined database for predictive microbiology (COMBASE)*. Available at:
<http://www.combase.cc/>
- **Joint FAO/WHO Expert Committee on Food Additives (JECFA).**
Publications available at:
www.who.int/foodsafety/chem/jecfa/publications/en/index.html
- **Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA).** Publications available at:
http://www.fao.org/ag/agn/agns/eims_search/advanced_s_result.asp?lang=en&oldquery=&announcement=&thecategory=&category_id=189,190,191,188,221&country=&actual_date=&RecordsPerPage=20&agrovoc=&form_c=AND

- **Joint FAO/WHO Meeting on Pesticide Residues (JMPR).** Publications available at:
<http://www.who.int/foodsafety/chem/jmpr/publications/en/index.html>
- **Joint FAO/WHO International Food Safety Authorities Network (INFOSAN).** Available at:
http://www.who.int/foodsafety/fs_management/infosan/en/
- **WHO.** 2009. *The manual for the public health management of chemical incidents.* Geneva, WHO. Available at:
http://www.who.int/environmental_health_emergencies/publications/Manual_Chemical_Incidents/en/
- **WHO.** 2010. Human Health Risk Assessment Toolkit. Geneva, WHO. Available at:
http://www.who.int/ipcs/methods/harmonization/areas/ra_toolkit/en/index.html
- **WHO.** Global Environment Monitoring System (GEMS)/Food. Available at:
<http://www.who.int/foodsafety/chem/gems/en/index1.html>

An essential part of the Food Safety Emergency Response (FSER) is the process of assessing the risk, making risk management decisions, and communicating risk in the face of time constraints, lack of data and knowledge gaps. While the elements for conducting a risk analysis have been documented by Codex Alimentarius, the process of applying the risk analysis concept operationally during an emergency has not been addressed thoroughly. Some countries do, however, have well-defined procedures for assessing, managing and communicating food safety risks in the context of emergency situations, from which best practices may be derived.

FAO and WHO have developed this document to support countries in applying risk analysis principles and procedures during emergencies in their own national food control systems, as risk analysis is a key component of national FSER planning.

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